

Appl. No. 09/912,448

Amendment dated January 3, 2006

Reply to Office action of October 3, 2005

REMARKS/ARGUMENTS

1. Claims 3-21 were previously pending. Claims 3-21 were rejected by the Office Action dated October 3, 2005.

Applicants hereby request further examination and reconsideration of the application, in view of the remarks.

2.
 - Claims 3-21 have been rejected under 35 U.S.C. 112, first paragraph.
 - Claims 3-21 have been rejected under 35 U.S.C. 103(a).

Rejection of Claims under 35 U.S.C.112, first paragraph

3. The Examiner has rejected Claims 3-21 under 35 U.S.C. 112, first paragraph, for containing New Matter, and being based on a non-enabling specification.

The Examiner states in the Office Action mailed October 3, 2005, that the "phrase 'not inhibitory' is still seen to be New Matter and not supported by the disclosure. This term has not been defined, so that it is not clear to what degree a composition would have to 'inhibit'. Also, the phrase is not clear as to what is being inhibited and under what conditions the 'inhibiting' is being measured against and in the amounts of product. For example, a dilute solution per carrier could be more 'inhibitory' in a larger amount per

weight of product to be treated. Also, although in applicants remarks filed 12/20/04, a

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further explanation in support of the recited ranges are given, the remarks are not seen to clearly point out the support for the overall range as recited" (Page 2, Final Office Action of October 3, 2005).

Applicant respectfully traverses the rejection. Matter that is added that makes explicit that which was implicit, inherent or intrinsic in the original disclosure is not new matter and is permitted. Thus, Applicant has particularly pointed to support in Example 2, Table 2; Example 3, Tables 3, 4, 5, and 7; Example 4, Table 9, and Example 5, Table 10. When one examines Table 2, reproduced below, one can see that with regards to "inhibition" the essential oils and different combinations of natural compounds, either inhibit spore germination 100% or do not inhibit at all, *i.e.*, inhibit 0%. With regard to *E. coli*, the essential oils do not inhibit (>600 CFU) or the combinations completely inhibit CFU, *i.e.*, there are zero (0) CFUs. Therefore, Applicant had stated in response to the Examiner's rejection in the First Office Action, "to clarify, the phrase "not inhibitory" means that a particular concentration of the component has no antibacterial or antifungal ability at all, *i.e.*, there is 0% inhibition or colony growth is not inhibited" (Page 9, Lines 1-3).

Table 2. Biocidal activity of essential oils and different combinations of natural compounds on spore germination of *B. cinerea* and growth of *E. coli* after 1 and 4 hr.

<u>Treatments</u>	<u>Inhibition (%)</u>		<u>Cell Counts (CFU)^a</u>	
	<u><i>B. cinerea</i></u>		<u><i>E. coli</i></u>	
	<u>1 hr</u>	<u>4 hr</u>	<u>1 hr</u>	<u>4 hr</u>
Control	0	0	TNTC ^b	TNTC
Chitosan sorbate	0	0	544	181

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Chitosan propionate	0	0	527	191
Cinnamon	0	100	>600	>600
Savory	0	0	>600	>600
Allspice	0	100	>600	>600
Chitosan sorbate + Cinnamon	100	100	0	0
Chitosan sorbate + Allspice	100	100	0	0
Chitosan propionate + Savory	100	100	0	0
Chitosan propionate + Red Thyme	100	100	0	0

^a Number of colony forming units (CFU) in 100 μ l sample.

^b TNTC=Too Numerous To Count.

Furthermore, the paragraph before Table 2 in the specification states, "In tests of the various essential oil/chitosan salt combinations against spore germination of *B. cinerea* and growth of *E. coli*, all four essential oil/chitosan salt combinations completely inhibited spore germination of *B. cinerea* and growth of *E. coli* (Table 2)" (Page 13, Lines 1-3). Thus, one could readily conclude that if "100% inhibition" and "0 CFU" referred to "completely inhibited", the only other number present, 0%, refers to "is not inhibitory". Thus, here, matter was added to the claim that makes explicit that which was implicit, inherent or intrinsic in the original disclosure and is therefore not new matter and is permitted.

Similarly, when other examples (Example 2, Table 2; Example 3, Tables 3, 4, 5, and 7; Example 4, Table 9, and Example 5, Table 10) that were cited for support (Amendment

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dated December 16, 2004, Page 6, Lines 11-15) are examined, evidence is clearly present to indicate what is or is not inhibitory, *i.e.*, what is "inhibitory" and "not inhibitory" is clearly stated and clearly disclosed in the specification. In any case, even if it were not explicitly stated, matter added to the claim that makes explicit that which was implicit, inherent or intrinsic in the original disclosure is not new matter and is permitted.

For example, in Example 3, "Inhibitory Effect of Essential Oils, Chitosan Salts, and Combinations of Essential Oils and Chitosan Salts" (beginning on Page 14), "the individual effects of various essential oils and chitosan salts, and the combined effects of essential oils and chitosan salts on the growth of the indicator organism *E. coli* and on the postharvest pathogen *B. cinerea* were determined"(Page 14).

"Effects on *E. coli* growth:

Savory, thyme red, and carvacrol, tested individually, were the most effective inhibitors of *E. coli* growth; **each, alone, was inhibitory at 0.05%** (Table 3). Cinnamon and hinokitiol reduced *E. coli* growth at 0.075%; no effects were seen at 0.05% or lower. Bay, cloves, allspice, and birch oil were the least effective inhibitors; they only inhibited at the final concentration of 0.1%. **No effects were observed at 0.075% or lower**" (Page 15).

"Table 3. Effect of Concentration of Essential Oil on Growth of *E. coli* (CFU^a)

<u>Essential Oil</u>	<u>Concentration (%v/v)</u>			
	<u>0.1</u>	<u>0.075</u>	<u>0.05</u>	<u>0.025</u>
Bay	13.5	TNTC	TNTC	TNTC
Cinnamon	0	61.5	TNTC	TNTC
Cloves	0	TNTC	TNTC	TNTC

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Allspice	0	TNTC	TNTC	TNTC
Thyme Red	0	4.5	0.5	TNTC
Savory	11.5	0	6.0	TNTC
Birch	0	TNTC	TNTC	TNTC
Carvacrol	0	0	0	TNTC
Hinokitiol	0	812	TNTC	TNTC

^a Number of colony forming units (CFU) in 100 μ l sample.^b TNTC=Too Numerous To Count" (Page 15).

"All chitosan salts were effective inhibitors of *E. coli* growth at concentrations of 0.1% - 0.0063%, but **no effect was seen with concentrations of 0.0032% or lower** (Table 4)" (Page 16).

"Table 4. Effect of Concentration of Chitosan Salts on Growth of *E. coli* (CFU^a)

	Concentration (%v/v)						
	<u>0.1</u>	<u>0.05</u>	<u>0.025</u>	<u>0.012</u>	<u>0.006</u>	<u>0.003</u>	<u>0.001</u>
				<u>5</u>	<u>3</u>	<u>2</u>	<u>6</u>
Chitosan-acetate	0	0	1	0	0	TNTC	TNTC
Chitosan-propionate	0	0.5	0.5	0	26	TNTC	TNTC
Chitosan-sorbate	0	0	0	0	4.5	TNTC	TNTC

^a Number of colony forming units (CFU) in 100 μ l sample.^b TNTC=Too Numerous To Count." (Page 16)

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Essential oils and chitosan salts, each at concentrations shown to be non-inhibitory in Tables 3 and 4, were combined with *E. coli* as described above and their effectiveness at inhibiting the growth of *E. coli* was measured. All combinations inhibited *E. coli* growth (Table 5). The individual essential oils and chitosan salts acted synergistically in combination; each inhibited in combination at concentrations where they were not individually inhibitory. Those essential oils that were found to be the least effective inhibitors of *E. coli* growth, as shown in Table 3, were effective inhibitors when tested together with chitosan salts.

Table 5. Effect of Synergistic Combinations of Essential Oils and Chitosan Salts on Growth of *E. coli* (CFU^a)

		Concentration (% v/v)			
		<u>Chitosan</u>	<u>Chitosan</u>	<u>Chitosan</u>	
		<u>acetate</u>	<u>propionate</u>	<u>sorbate</u>	
	<u>Conc. (%)</u>	<u>0.0032</u>	<u>0.0032</u>	<u>0.0032</u>	<u>Water</u>
Water		TNTC	TNTC	TNTC	TNTC
Bay	0.075	75	180	479	TNTC
Cinnamon	0.050	401	582	793	TNTC
Savory	0.025	1803	691	1614	TNTC
Thyme Red	0.025	1044	115	1328	TNTC
Allspice	0.075	0	20	32	TNTC
Birch	0.075	640	1621	2713	TNTC

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Cloves	0.075	34	83	193	1212
Carvacrol	0.025	0	0	2	1430
Hinokitiol	0.075	102	56	60	1108

^a Number of colony forming units (CFU) in 100 μ l sample.

^b TNTC=Too Numerous To Count.

Similar results were observed when spore germination of *B. cinerea* was measured (Tables 6, 7, and 8). The individual essential oils: bay, cinnamon, allspice and cloves were inhibitory at 0.05%; savory and thyme red were inhibitory only at 0.1% (Table 6) (Page17, Lines21-23).

Chitosan-sorbate alone was effective in **completely inhibiting** *B. cinerea* spore germination at concentrations of 0.1% to 0.0175% (Table 7). **Complete inhibition** of spore germination of *B. cinerea* was obtained with chitosan-acetate and chitosan-propionate at 0.1% and 0.08% (Page 18, Lines14-17).

"Table 7. Effect of Concentrations of Chitosan Salts on Spore Germination of *B. cinerea*.

	Percent Inhibition of Spore Germination							
	Concentration (% v/v)							
	<u>0.1</u>	<u>0.08</u>	<u>0.06</u>	<u>0.04</u>	<u>0.02</u>	<u>0.0175</u>	<u>0.015</u>	<u>0.0125</u>
Chitosan-acetate	100	100	0	0	0	0	0	0
Chitosan-propionate	100	100	0	0	0	0	0	0
Chitosan-sorbate	100	100	100	100	100	100	0	0

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Essential oils and chitosan salts, each at concentrations shown to be non-inhibitory in Tables 6 and 7, were combined with *B. cinerea*, as described above, and their effectiveness at inhibiting spore germination of *B. cinerea* was measured. All combinations of essential oils and chitosan salts, at concentrations where they were not individually inhibitory, showed a synergistic effect and completely inhibited *B. cinerea* spore germination (Table 8). Those essential oils that were found to be the least and the most effective inhibitors of *B. cinerea* spore germination (Table 6) were equally effective when tested together with chitosan salts even though both the essential oil and the chitosan salt were present at concentrations where no inhibition had previously been observed (Tables 6 and 7)"(Page18, Line 19 - Page 19, Line 10).

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Table 8. Effect of Synergistic Combinations of Essential Oils and Chitosan Salts on Spore Germination of *B. cinerea*.

		Percent Inhibition of Spore Germination			
		Concentration (% v/v)			
	<u>Conc.</u>	<u>Chitosan</u>	<u>Chitosan</u>	<u>Chitosan</u>	
	<u>% (v/v)</u>	<u>acetate</u>	<u>propionate</u>	<u>sorbate</u>	<u>Water</u>
		<u>0.02</u>	<u>0.02</u>	<u>0.006</u>	
Bay	0.013	100	100	100	0
Cinnamon	0.013	100	100	100	0
Savory	0.03	100	100	100	0
Thyme Red	0.03	100	100	100	0

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Allspice	0.02	100	100	100	0
Cloves	0.01	100	100	100	0
Hinokitiol	0.067	100	100	100	0

Further, with regard to the ranges recited in the claims, it is stated in the MPEP (MPEP 2163.05) that with regard to New Matter "the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure. In the decision in *In re Wertheim*, 541 F2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of '25% -60%' and specific examples of '36%' and '50%'. A corresponding new claim limitation to 'at least 35%' did not meet the description requirement because the phrase 'at least' had no upper limit and caused the claim to read literally on embodiments outside the '25% to 60%' range, however, a limitation to "between 35% and 60%" did meet the description requirement".

In the instant case, Claim 21 recites a "composition which has protectant and/or eradicator activity and which substantially inhibits bacterial and fungal growth, comprising a chitosan salt and an essential oil in a synergistically effective amount wherein the chitosan salt is present in an amount which is not inhibitory in the absence of the essential oil, wherein the concentration of the chitosan salt is in the range of 0.0016 - 0.1% (v/v), and wherein the essential oil is present in an amount which is not inhibitory in the absence of the chitosan salt, wherein the concentration of the essential oil is in the range of 0.025 - 0.1% (v/v)."

With regard to the recitations of "the concentration of the chitosan salt is in the range of

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0.0016 - 0.1% (v/v)" and "the concentration of the essential oil is in the range of 0.025 - 0.1% (v/v)", the Examiner has indicated that "a more detailed analysis of the specification is necessary." In addition to the examples which were particularly pointed to and highlighted, the specification discloses, "[A]s used herein, the term "synergism" is intended to include both an increased spectrum of activity (*i.e.*, greater activity against a broad spectrum of microorganisms), and/or increased efficacy (*i.e.*, greater activity against specific organisms than that predicted by use of either agent alone). The increased antimicrobial and antifungal activity of the synergistic combination permits the **use of smaller amounts of each agent thereby decreasing costs and minimizing other problems, e.g., toxicity, solubility, availability.** Effectiveness against a broad spectrum of microorganisms broadens the utility of the synergistic product based on its effectiveness in environments containing many and diverse microorganisms which must be controlled" (Page 6, Lines 8-15). The specification also discloses that it "it is an object of the invention to provide a composition of natural compounds that act synergistically and are effective against postharvest pathogens and foodborne pathogens found on fruits and vegetables" (Page 4, Lines 1-3); that the present invention provides combinations of chitosan salts and essential oils that act synergistically both to protect food products from bacterial and fungal contamination and to eradicate or at least inhibit growth and toxin production in foods contaminated with bacteria and fungi (Paragraph bridging Pages 4 and 5); and that "[D]evelopment of synergistic combinations of natural compounds can add a new dimension to their use as food preservatives, enhancing their effectiveness for stability, low toxicity, availability, and broad utility (Page 3, Lines 20-22).

Thus, Applicants have indicated that it is an object of the invention to use smaller amounts of chitosan salts and essential oils that act synergistically. The specification teaches that particular concentrations of chitosan acetate, chitosan propionate, and chitosan sorbate **do not inhibit *B. cinerea* spore germination or growth of *E. coli* colonies.**

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For example, in Example 2, Table 2, that chitosan sorbate and chitosan propionate at a 0.1% concentration do not inhibit *B. cinerea* (there is 0% inhibition of spore germination) or *E. coli*. (there are hundreds of CFU). In Example 3, Table 4, concentrations of chitosan acetate, chitosan propionate, and chitosan sorbate at 0.0016 and 0.0032% **did not inhibit at all, i.e.,** the colony number was too numerous to count. In Example 3, Table 7, concentrations of chitosan acetate at 0.06% (v/v) or less **did not inhibit at all**; concentrations of chitosan propionate at 0.06% (v/v) or less **did not inhibit at all**; and concentrations of chitosan sorbate at 0.015 % (v/v) **did not inhibit at all, i.e.,** spore germination occurred in the presence of those concentrations. Table 10 shows that apples treated with 0.1% concentrations of chitosan sorbate and chitosan propionate, either before or after exposure to *E. coli* cultures, **do not inhibit growth of E. coli colonies.**

Similarly, with regard to the recitation that "the concentration of the essential oil is in the range of 0.025 - 0.1% (v/v)," Table 5 discloses savory, thyme red, and carvacrol at concentrations of 0.025% (v/v), cinnamon, at 0.050% (v/v), and bay, allspice, birch, cloves, and hinokitiol at 0.075% (v/v). As shown in Table 3, savory, thyme red, and carvacrol **do not inhibit at all** at concentrations of 0.025% (v/v). Table 3 also shows that cinnamon **does not inhibit at all** at concentrations of 0.050% (v/v) or lower and that bay, allspice, birch, cloves, and hinokitiol **do not inhibit at all** at concentrations of 0.075% (v/v) or lower. Table 2 shows that cinnamon, savory, and allspice **do not inhibit growth** of *E. coli* colonies at all when used at a concentration of 0.1% (v/v).

Therefore, Table 5 shows that examples of chitosan salts: chitosan acetate, chitosan proprionate, and chitosan sorbate, when used at a concentration that is not inhibitory at all, i.e., 0.0032% (v/v) (as shown in Table 4) together with essential oils at concentrations that are not inhibitory at all (as shown in Table 3) act

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synergistically to inhibit growth of *E. coli* colonies. Similar results were observed when spore germination of *B. cinerea* was measured after determining appropriate low concentrations by a similar strategy; see Tables 6, 7, and 8.

Thus, the composition of Applicant comprises concentrations of essential oils and chitosan that absolutely do not inhibit by themselves, but inhibit totally or substantially when combined, *i.e.*, they act synergistically. Combining two substances in non-inhibitory concentrations, unexpectedly results in a synergistic response as discussed in the above examples.

The Examiner asserts that "Applicant has attempted to define a term after the fact, if you will. The specification as originally filed does not define what is meant by 'not inhibitory' – either in degree of inhibition, what is being inhibited, and under what conditions this inhibiting takes place. One cannot impart a definition to a term, after the application has been filed, if the specification does not necessarily and inherently support the definition. As noted above, the phrase is not supported by a clear definition in the specification, so that it is non-enabling" (Paragraph bridging Pages 2 and 3, Final Office Action of October 3, 2005). The citations and examples from the specification cited by Applicant clearly show the Examiner's assertions to be unsupported.

In view of the amendment and the above remarks, it is respectfully requested that the rejection of Claims 3-21 under 35 U.S.C. 112, first paragraph, be withdrawn.

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Rejection of Claims 3, 6-9, 14 and 15 under 35 U.S.C.103(a)

4. The Examiner has rejected Claims 3-21 under 35 U.S.C. 103(a) as being unpatentable over Takahashi (U.S. Patent 6,352,727, 2002) in view of Ozawa (JP 10-195,766), Atsumi *et al.* (JP 200217509), and Packpla (1996, Vol. 40, No. 1, pages 132-138).

The Examiner states that "Takahashi discloses a concentration within the recited range (e.g. .1% vol.) and states that they can be mixed at any ratio. Note, too, that Takahashi discloses that the two ingredients can be varied suitable depending on how it is to be used and the dosage form. See, in this regard, col. 5, para. 6" (Page 2, Final Office Action of October 3, 2005). The Examiner continues, "Takahashi discloses broad ranges of concentration of the components, which ranges appear to fall within the recited range. Since the recited ranges appear to overlap with those of Takahashi, then the ranges of Takahashi inherently meet the phrasing in question (i.e. not inhibitory)". However, as noted above and previously, this phrasing is unclear and is readable on varying degrees of effectiveness of the components such as: not inhibitory, relative to their combination together. Further, even if the ranges did not overlap, Takahashi discloses that combining the components impart a synergistic result, and taken with the art taken as a whole, including Atsumi who applicant admits also discloses synergistic results with the combined ingredients, would fairly lead one of ordinary skill in the art, through routine experimentation, to determine all ranges of synergism" (Page 3, Final Office Action of October 3, 2005).

Applicant respectfully traverses the rejection. Applicant respectfully disagrees with the Examiner's assertion that a *prima facie* case of obviousness has been established. It is stated in the MPEP (MPEP 706.02(j) that "[T]o establish a *prima facie* case of

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obviousness three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references to combine reference teachings. Second, there must be reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure."

"The prior art reference (or references when combined) must teach or suggest all the claim limitations." Claim 21 recites a composition which has protectant and/or eradicator activity and which substantially inhibits bacterial and fungal growth, comprising a chitosan salt and an essential oil in a synergistically effective amount wherein the chitosan salt is present in an amount which is not inhibitory in the absence of the essential oil, wherein the concentration of the chitosan salt is in the range of 0.0016 - 0.1% (v/v), and wherein the essential oil is present in an amount which is not inhibitory in the absence of the chitosan salt, wherein the concentration of the essential oil is in the range of 0.025 - 0.1% (v/v). The references cited by the Examiner do not teach or suggest all claim limitations.

As Applicant has stated above, "to clarify, the phrase 'not inhibitory' means that a particular concentration of the component has no antibacterial or antifungal ability at all, i.e., there is 0% inhibition or colony growth is not inhibited." In Applicant's response above to the rejection under 35 U.S.C. 112, first paragraph, Applicant has pointed to support in the specification: "the specification teaches that particular concentrations of chitosan acetate, chitosan propionate, and chitosan sorbate do not inhibit *B. cinerea* spore germination or growth of *E.coli* colonies. For example, in Example 2, Table 2, that chitosan sorbate and chitosan propionate at a 0.1% concentration do not inhibit *B.*

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cinerea (there is 0% inhibition of spore germination) or *E.coli*. (there are hundreds of CFU). In Example 3, Table 4, concentrations of chitosan acetate, chitosan propionate, and chitosan sorbate at 0.0016 and 0.0032% did not inhibit at all, *i.e.*, the colony number was too numerous to count. In Example 3, Table 7, concentrations of chitosan acetate at 0.06% (v/v) or less did not inhibit at all; concentrations of chitosan propionate at 0.06% (v/v) or less did not inhibit at all; and concentrations of chitosan sorbate at 0.015 % (v/v) did not inhibit at all, *i.e.*, spore germination occurred in the presence of those concentrations. Table 10 shows that apples treated with 0.1% concentrations of chitosan sorbate and chitosan propionate, either before or after exposure to *E. coli* cultures, do not inhibit growth of *E. coli* colonies.

Similarly, with regard to the recitation that "the concentration of the essential oil is in the range of 0.025 - 0.1% (v/v)." Table 5 discloses savory, thyme red, and carvacrol at concentrations of 0.025% (v/v), cinnamon, at 0.050% (v/v), and bay, allspice, birch, cloves, and hinokitiol at 0.075% (v/v). As shown in Table 3, savory, thyme red, and carvacrol do not inhibit at all at concentrations of 0.025% (v/v). Table 3 also shows that cinnamon does not inhibit at all at concentrations of 0.050% (v/v) or lower and that bay, allspice, birch, cloves, and hinokitiol do not inhibit at all at concentrations of 0.075% (v/v) or lower. Table 2 shows that cinnamon, savory, and allspice do not inhibit growth of *E. coli* colonies at all when used at a concentration of 0.1% (v/v).

Therefore, Table 5 shows that examples of chitosan salts: chitosan acetate, chitosan propionate, and chitosan sorbate, when used at a concentration that is not inhibitory at all, *i.e.*, 0.0032% (v/v) (as shown in Table 4) together with essential oils at concentrations that are not inhibitory at all (as shown in Table 3) act synergistically to inhibit growth of *E. coli* colonies. Similar results were observed when spore germination of *B. cinerea* was measured after determining appropriate low concentrations by a similar strategy; see

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Tables 6, 7, and 8.

Thus, the composition of Applicant comprises concentrations of essential oils and chitosan that absolutely do not inhibit by themselves, but inhibit totally or substantially when combined, *i.e.*, they act synergistically. Combining two substances in non-inhibitory concentrations, unexpectedly results in a synergistic response as discussed in the above examples".

There is nothing in Takahashi which teaches the limitations (concentrations and conditions) of the instant claims and the concentrations of the chitosan salt (or chitosan) and the essential oil in Takahashi do not inherently meet the concentrations and conditions of the claims. When compared to Takahashi's ranges, the claimed range of much lower concentrations of Applicant thus results in an unexpected outcome. Takahashi never discloses, recites, or considers the low concentrations of Applicant; Takahashi claims success with the "additive" effects of combining much higher concentrations of chitosan and essential oil.

5. As stated above, the Examiner alleges that "Takahashi discloses broad ranges of concentration of the components, which ranges appear to fall within the recited range. Since the recited ranges appear to overlap with those of Takahashi, then the ranges of Takahashi inherently meet the phrasing in question (*i.e.* 'not inhibitory'). However, as noted above and previously, this phrasing is unclear and is readable on varying degrees of effectiveness of the components such as: not inhibitory, relative to their combination together. Further, even if the ranges did not overlap, Takahashi discloses that combining the components impart a synergistic result, and taken with the art taken as a whole, including Atsumi who applicant admits also discloses synergistic results with the

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combined ingredients, **would fairly lead one of ordinary skill in the art, through routine experimentation, to determine all ranges of synergism**" (Page 3, Final Office Action of October 3, 2005).

Applicant respectfully traverses the rejection. Applicant respectfully disagrees with the Examiner's assertion that the selection of the particular concentrations of the components to provide a synergistic result would have been obvious routine determination. The Examiner has provided no evidence that Takahashi or Atsumi *et al.* would utilize the concentrations of the instant invention to obtain a synergistic combination. Takahashi having achieved satisfaction and success with the "additive" effects of much higher concentrations, **essentially teaches away from combining the very low concentrations of Applicant. Thus, the ranges of Applicant cannot be considered obvious over Takahashi.**

Furthermore, the Examiner now states that the "American Heritage Dictionary defines as synergism which in turn is defined as the action of two or more substances, organs, or organisms to achieve an effect of which each is **individually incapable**" (Page 4, Final Office Action of October 3, 2005). In fact, the teachings of Takahashi do not meet the definition set forth by the Examiner; the concentrations of Takanashi each individually have an effect, *i.e.*, each is "**individually capable**". Further, there is nothing the teachings of Ozawa *et al.* or Atsumi *et al.* which overcomes the deficiencies of the Takahashi reference.

The composition of Applicant, however, comprises concentrations of essential oils and chitosan that absolutely do not inhibit by themselves, but inhibit totally or substantially when combined, *i.e.*, they act synergistically. Combining two substances in non-inhibitory

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concentrations, unexpectedly results in a synergistic response. See, for example, Tables 6 and 8, Pages 18 and 19.

Thus, the prior art reference (or references when combined) do not teach or suggest all the claim limitations.

6. Therefore, taking the following facts into account: (1) the absence in Takahashi, Ozawa *et al.*, or Atsumi *et al.* of a teaching of a composition which has protectant and/or eradicator activity and which substantially inhibits bacterial and fungal growth, comprising a chitosan salt and an essential oil in a synergistically effective amount wherein the chitosan salt is present in an amount which is not inhibitory in the absence of the essential oil, wherein the concentration of the chitosan salt is in the range of 0.0016 - 0.1% (v/v), and wherein the essential oil is present in an amount which is not inhibitory in the absence of the chitosan salt, wherein the concentration of the essential oil is in the range of 0.025 - 0.1% (v/v), (2) the lack of a teaching of the motivation to combine the references and (3) the absence of a reasonable expectation of success to obtain particular synergistic combinations and concentrations, it would not have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have obtained the claimed invention.

In view of the above, it is respectfully requested that the rejection of Claims 3-21 under 35 U.S.C. paragraph 103 be withdrawn.

7. The Examiner has stated that it is "noted that applicant apparently has obtained a translation of Atsumi. If applicant continues prosecution of this application, by filing a

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response, applicant is asked to submit a copy of the translation for the record" (Page 3, Final Office Action of October 3, 2005). Thus, it is respectfully assumed by Applicant, based on the Examiner's request, that the Examiner, on the record, has cited Atsumi, a Japanese patent, written in Japanese, as a reference in the rejection under 35 U.S.C. 103(a) without obtaining a translation.

The Examiner is respectfully reminded that "Examiners may consult the translators in the ***>Translations< Branch of **>STIC<** for oral assistance in translating foreign language patents and other literature sources **that are possible references for applications being examined**. Oral translations are performed for the major European languages and for Japanese. **Examiners may also request written translations of pertinent portions of references being considered for citation or already cited in applications. Full translations are also made upon request. Written translations can be made from virtually all foreign languages into English. >See also MPEP § 901.05(d).<**" See MPEP §901.06(a).

However, in the interest of moving prosecution forward, Applicant is providing, as Attachment 1, the translation that Applicant obtained from the translation service (computer translated) of the Japanese Patent Office website.

CONCLUSION

Please charge any additional fees which may be required at any time during prosecution of the instant application to deposit account 50-2134.

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In view of the above remarks, it is believed that all of the claims and the specification are in condition for allowance. Accordingly, it is respectfully requested that the rejections be withdrawn and that the instant application be allowed to issue. If any issues remain to be resolved, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

January 3, 2006
Date

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